MAR - 3 2008

K072816

5. 510(k) Summary *Document template QAF-300079-00*	Sundbybergsvägen 9 PO Box 1024 SE-171 21 Solna, Sweden phone +46 8 629 0780 fax +46 8 629 0781 www.aerocrine.com org.no 556549-1056 VAT No: Reg. Office Stockholm, SE556549105601 **Aerocrine**

Product: NIOX MINO®		Structure/module:		
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List of receivers:		Key words:		

Proposed draft

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Summary preparation date: Revised:	2007-09-25 2008-01-03

Name of the Device

Trade name	NIOX MINO®
Common/Generic Device Name	Airway inflammation monitor
Classification Name	Breath Nitric Oxide Test System
Device Class	II
Product Code	MXA
Regulation number	21 CFR 862.3080
Medical Speciality	CH, Clinical Chemistry
Owner/Operator	AEROCRINE AB
Owner/Operator number	9057041
Establishment Operations	Specification Developer, Manufacturer

Predicate Device

Trade Name of Predicate Device	NIOX®
Common/ Generic Device Name	Nitric Oxide Breath Analyzer
Classification Name	Breath Nitric Oxide Test System
Device Class	II
Product Code	MXA
Regulation number	21 CFR 862.3080
Medical Speciality	CH, Clinical Chemistry
Owner/Operator	AEROCRINE AB
Owner/Operator number	9057041
Establishment Operations	Specification Developer, Manufacturer
510(k) Number	K021133

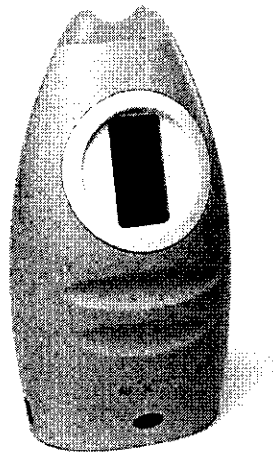

Figure 1 NIOX MINO® Airway Inflammation Monitor

Device Description

NIOX MINO® Airway Inflammation Monitor is a hand held device intended to measure fractional exhaled nitric oxide in human breath in ppb levels (parts per billion), complying with 21 CFR 862.3080.

NIOX MINO Airway Inflammation Monitor is manufactured by Aerocrine AB, Sweden. For NIOX MINO Airway Inflammation Monitor, Aerocrine AB claims substantial equivalence to the predicate device NIOX® Nitric Oxide Monitoring System (K021133).

The intended use for NIOX MINO Airway Inflammation Monitor is the same as the intended use for NIOX, Nitric Oxide Monitoring System. The performance characteristics for NIOX MINO Airway Inflammation Monitor and NIOX Nitric Oxide Monitoring System are substantially equivalent as shown in laboratory and clinical tests.

Intended use

NIOX MINO® measures Nitric Oxide (NO) in human breath. Nitric Oxide is frequently increased in some inflammatory processes such as asthma. The fractional NO concentration in expired breath (FE_{NO}), can be measured by NIOX MINO® according to guidelines for NO measurement established by the American Thoracic Society.

Measurement of FE_{NO} by NIOX MINO® is a quantitative, non-invasive, simple and safe method to measure the decrease in FE_{NO} concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FE_{NO} levels. NIOX MINO® is suitable for children, approximately 7 - 17 years, and adults 18 years and older.

FE_{NO} measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. NIOX MINO® should only be used as directed in the NIOX MINO User Manual and the NIOX MINO Quality Control Test User Manual, by trained physicians, nurses, respiratory therapists or laboratory technicians. NIOX MINO® cannot be used with infants or by children approximately under the age of 7, as measurement requires patient cooperation. NIOX MINO® should not be used in critical care, emergency care or in anaesthesiology.

Technological characteristics

Table 5-1

Characteristic	NIOX MINO®	NIOX®
Device type	Device for regular clinical practice. Point of care.	Device for regular clinical practice. Not portable.
Target population	Suitable for children, 7 - 17 years, and adults 18 years and older.	Suitable for children, 4 - 17 years and adults 18 years and older.
Dimensions and weight	Height 240 mm Width 130 mm Depth 100 mm Weight 0.8 kg	Height 500 mm Width 300 mm Depth 400 mm Weight 40 kg
Measurement method	Electrochemical detection	Chemiluminescence detection
Measurement range	5 - 300 ppb	2 - 200 ppb
Detection level (analytical sensitivity)	5 ppb	2 ppb
Linearity	Squared correlation coefficient $r^2 \geq 0.998$, Determination based on the regression analysis using standard gas reference samples at different concentration levels covering the operating measurement range.	Integral linearity < 2.5 ppb Determination based on the regression analysis using standard gas reference samples at different concentration levels covering the operating measurement range.
Precision	Analytical precision: < 3 ppb of measured value < 30 ppb, < 10 % of measured value ≥ 30 ppb. Expressed as one standard deviation for replicate measurements with the same instrument, using a certified gas concentration of Nitric Oxide reference standard. Clinical precision: < 3 ppb of measured value < 30 ppb The clinical precision for values ≥ 30 ppb has not been established.	Analytical precision: < 2.5 ppb of measured value < 50 ppb < 5 % of measured value > 50 ppb Expressed as one standard deviation for concentrations below 50 ppb and coefficient variation for concentrations above 50 ppb. Clinical precision: < 2.5 ppb of measured value < 50 ppb Clinical precision has not been evaluated for FE_{NO} values > 50 ppb.
Accuracy	Analytical Accuracy ± 5 ppb or max 15 % Based on mean of absolute differences from certified gas concentration of Nitric Oxide reference standard. (95% CI)	Analytical accuracy ± 2.5 ppb of measured value < 50 ppb, ± 5% of measured value > 50 ppb Based on mean of absolute differences from certified gas concentration of Nitric Oxide reference standard.
Method Comparison	± 5 ppb for values < 50 ppb, Expressed as the difference, using one standard deviation, between a NIOX MINO FE_{NO} value and the corresponding FE_{NO} value measured with NIOX instrument from Aerocrine.	

Non-clinical studies performed

Extensive performance testing has been performed to support substantial equivalence.
Linearity, precision and accuracy has been evaluated according to laboratory standard NCCLS EP9-P
The variation between individual instruments during long-time use under various climate conditions has been studied.

The results from the performance testing support substantial equivalence between NIOX MINO and NIOX.

Clinical studies performed

Multi-center clinical studies have been performed to validate the intended use and verify substantial equivalence to the predicate device.

Clinical studies demonstrated that NIOX MINO is a quantitative, non-invasive, simple and safe method to measure the decrease in FE_{NO} concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy, as an indication of the therapeutic effect in patients with elevated FE_{NO} levels. NIOX MINO has been shown to be suitable for children, 7 - 17 years, and adults 18 years and older.

The normal range for nitric oxide in exhaled breath, exhalation flow rates, length of exhalation, differences in levels due to gender, size, and ethnicity and other such aspects are being continuously discussed, for values and statistical details, kindly consult the official Product Labelling.

It has been demonstrated that only one measurement is sufficient in NIOX MINO to obtain reliable results. For details, kindly consult the Users Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Aerocrine AB
c/o Mr. Joel Slomoff, Consultant
Fulbright & Jaworski LLP
801 Pennsylvania Avenue
Washington, DC 20004

MAR - 3 2008

Re: k072816
Trade Name: Niox Mino™
Regulation Number: 21 CFR 862.3080
Regulation Name: Breath nitric oxide test system.
Regulatory Class: Class II
Product Codes: MXA
Dated: February 27, 2008
Received: February 27, 2008

Dear Mr. Slomoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K072816

Device Name: NIOX MINO®

Indication For Use:

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FE_{NO} measurements provide the physician with means of evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to the established clinical and laboratory assessments in asthma. NIOX MINO should only be used as directed in the NIOX MINO User Manual and the NIOX MINO Quality Control Test User Manual, by trained physicians, nurses, respiratory therapists and laboratory technicians. NIOX MINO cannot be used with infants or by children approximately under the age of 7, as measurement requires patient cooperation. NIOX MINO should not be used in critical care, emergency care or in anaesthesiology.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072816